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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,338	04/09/2004	Christa Harris	THR-6216	1230

7590 07/29/2005

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EXAMINER

ROANE, AARON F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/821,338	<b>Applicant(s)</b> HARRIS ET AL.	
	<b>Examiner</b> Aaron Roane	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/31/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitahara et al.

(USPN 5,261,241) in view of Maro et al. (USPN 5,491,018) and in further view of Helmeg (USPN 6,648,909 B2).

Regarding claims 1 and 3-7, Kitahara et al. disclose a topically applied thermal device (13) comprising a flexible plastic containment (10, 12 and 14) and activatable thermochemical liquid composition (C not shown in figure 2) encased therein, said flexible plastic containment comprising a multilayer film (10, 12 and 14) comprising: an outer polymeric barrier layer (12) comprising a coating (10), and an inner polymeric sealant layer (14). Kitahara et al. further disclose that the outer polymeric layer is comprised a layer of polyester (12) coated with a layer of aluminum (12) in order to provide the device with a liquid impervious, leak proof layer see col. 5, lines 29-61, col.

10 and figure 2. Kitahara et al. fail to disclose that the coating is either aluminum oxide or silicon oxide coating. Kitahara et al. also fail to disclose that the inner polymeric sealant layer comprises a blend of low density polyethylene (LDPE) and ethylvinyl acetate (EVA). Maro et al. disclose a laminated packing material and teach the coating of polyester with a silicon oxide layer in order to provide the device with a liquid impervious, leak proof layer, see col. 1-12. Helmeg discloses a hot/cold pack and teaches the use of making a inner layer, seal and/or bag from LDPE in order to provide a burstable/rupturable barrier to the device, see col. 1-6 and figures 1-9. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Kitahara et al., as taught by Maro et al., to coat the polyester layer with a silicon oxide layer in order to provide the device with a liquid impervious, leak proof layer, and as further taught by Helmeg, to make the inner layer, seal and/or bag from LDPE in order to provide a burstable/rupturable barrier to the device. Finally, at the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use an inner polymeric sealant layer comprised of low density polyethylene (LDPE) because Applicant has not disclosed that an inner polymeric sealant layer comprising a blend of low density polyethylene (LDPE) and ethylvinyl acetate (EVA) provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with only the LDPE because it also provides the burstable/rupturable capabilities.

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Regarding claim 2, Kitahara et al. further disclose a device comprising an adhesive layer laminating together said outer polymeric barrier layer and said inner polymeric sealant layer, see col. 6.

Regarding claim 8, Kitahara et al. disclose the claimed invention, see col. 1-16.

Regarding claims 9 and 10, Kitahara et al. disclose the claimed invention, see col. 1-16.

### *Response to Amendment*

The examiner acknowledges the amendment made to page 3 of the specification regarding Applicant's the co-pending US patent application Serial No. 10/821,694.

### *Response to Arguments*

Applicant's arguments filed 5/21/2005 have been fully considered but they are not persuasive.

The examiner will address each argument/remark in turn.

Beginning on page 6, the second to the last line and continuing until page 7, line 7 Applicant asserts that an "activatable thermochemical liquid composition ..... differs from a

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separated first solid or liquid ingredient and a second liquid ingredient that require combination/mixture to be activated.” However, Applicant has not provided a restrictive definition that would provide guidance to the examiner such that the broad interpretation of the previous and present office action and the prior art of record is or would be precluded. Therefore the “separated first solid or liquid ingredient and a second liquid ingredient” (as characterized by Applicant) is an “activatable thermochemical liquid composition.” Next, Applicant points out that the presently claimed invention has no “burstable or rupturable” casing and that this feature “is repugnant to Applicants invention and advantages.” However the prior art (specifically, Kitahara et al. and Helmeg) disclose “burstable or rupturable” seals/membranes. Again, as there is no claim language that precludes the use of and/or recitation of “burstable or rupturable” seals/membranes, the examiner and office may be inclined to use such prior art. Regarding both points, 1) “activatable thermochemical liquid composition” and 2) “burstable or rupturable” seals/membranes, although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

Next Applicant the Kitahara et al. reference as not disclosing a topically applied device, see page 7, 2<sup>nd</sup> paragraph. First, the device disclosed by Kitahara et al. is certainly capable of being topically applied. The fact that Applicant claims a “topically-applied thermal device” in and of itself does not preclude the (proper) use of prior art that (albeit) is silent of topical application from serving in rejections thereto particularly when the prior art is capable of topical application. Although “topically-applied thermal device” breathes life into the body of the

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claim, it provides no limitations which preclude the use of the Kitahara et al. reference.

Applicant has question “the examiner’s reference to the teaching of aluminum” coating of Kitahara et al. and how it relates to the presently claimed invention. The disclosure of an aluminum coating and the motivation for using it by Kitahara et al. clearly serves to further support the motivation for combining the Maro et al. reference and its teaching. In the 3<sup>rd</sup> paragraph of page 7, Applicant refutes the use of Maro et al. and does not understand “why one of ordinary skill in the art would view a packaging material and have been lead to a topical thermal therapy device.” Again, as explained clearly above and combination of Kitahara et al. and Maro et al. is clearly motivated by their shared desire to limit liquid seepage/leakage and/or evaporation via the use of particular coatings.

Finally the examiner wishes to remind Applicant of issues that may help Applicant better understand the examiner’s application of prior art. First, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F. 2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). Secondly, although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be

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fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

**This action is made FINAL.**

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*  
July 26, 2005

*Roy D. Gibson*  
**ROY D. GIBSON**  
**PRIMARY EXAMINER**